



PLASTIC SURGERY  
EDUCATIONAL FOUNDATION



THE AMERICAN SOCIETY FOR  
AESTHETIC PLASTIC SURGERY, INC.

# *The Silicone Breast Implant* *Education Symposium*

Manufacturing, Materials Science And Mechanical Properties

ASPS/PSEF – ASAPS

V. Leroy Young, MD

V.L. Young, MD, 04/04 - DRAFT

# Topics

- Chemistry of silicones
- Biocompatibility
- Design
- Fillers and shells
- Production processes
- Testing and quality control
- Packaging and sterilization
- Labeling and tracking

# *Chemistry of Silicone*

- Silicon
- Silica
- Silicone

# *Silicon (Si)*

- Semi-metallic element
- Second most abundant substance in earth's crust (after oxygen)
  - Also a trace element in plants and animals
- Not found in nature in its elemental form but reduced from natural silicas (silicon oxides)

# *Silica ( $\text{SiO}_2$ – Silicon Dioxide)*

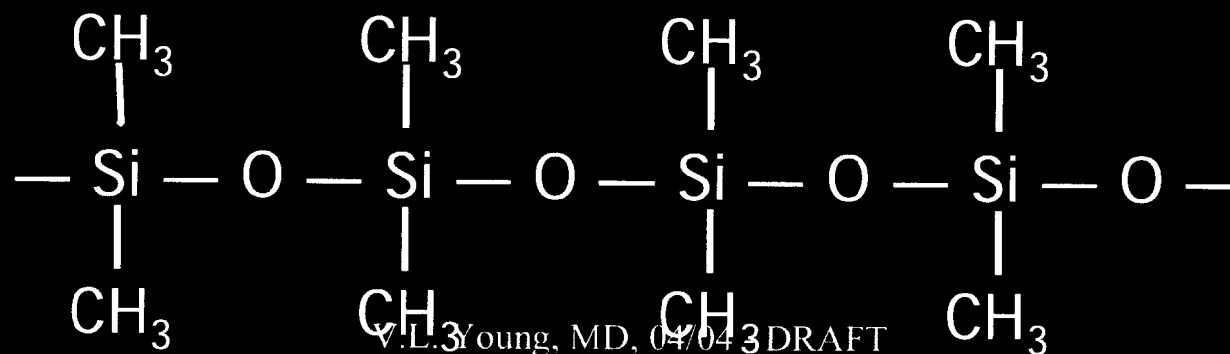
- Insoluble in water and chemically inert
- Very common mineral found naturally in crystalline and amorphous forms
- Sand and quartz are nearly pure crystalline forms of silica

## *Silica ( $\text{SiO}_2$ – Silicon Dioxide)*

- Amorphous silica has same basic atomic structure as crystalline form but lacks highly ordered geometry
- Used as desiccants, adsorbents, reinforcing agents, builders for detergents, binders, and catalyst components

# Chemistry of Silicone

- Large family of organic polymers with a repeating backbone of alternating Si and O atoms
  - Organic groups attach directly to the Si atom via silicon-carbon bonds
- Polydimethylsiloxane (PDMS) ↙ methyl group



# *Chemistry of Silicone*

- Chains of PDMS can be linked together to form a polymer network
  - Process called crosslinking or curing
- Chemical reaction occurs between an Si-vinyl group on one chain and a hydrogen atom bonded to Si on another chain
- Gel and elastomer are composed of the PDMS polymer, crosslinker, and catalyst



# *Chemistry of Silicone*

- Crosslinkers are shorter-chained polymers
- Catalyst used to cure gel & elastomer for gel-filled implants is typically platinum
  - very little catalyst is needed for curing
  - gel often contains <15 ppm platinum
- Catalyst used to cure elastomer shell for saline-filled implants is often tin

# *Silicone Fluids / Oils*

- Molecules are arranged in linear chains, with viscosity dependent on chain length
- Straight chains may range from <10 to many thousand Si-O units

# *Silicone Gels*

- Molecules are crosslinked to branch into a semi-liquid 3-D polymer network
  - more branching produces thicker gels
- Network is swollen with PDMS fluid to produce a sticky, cohesive mass
- Silica is never added to gel

# *Elastomers (Rubbers)*

- Long chain PDMS fluid is joined for side bonding
- Much more densely crosslinked than gel
- Special forms of amorphous silica are added and tightly bound into the polymer network
- Silica reinforcement gives elastomer its strength and extensibility

# Comparative Polymer Viscosity

Degree of polymerization	viscosity centistokes	comparative viscosity
3	1.04	water
30	9.44	baby oil
269	100	olive oil
591	335.3	heavy motor oil
960	10,000	honey
1400	1,000,000	PDMS rubber
2600	10,000,000	hot asphalt

# Physical & Chemical Properties

- Thermal and oxidative stability
- Physical properties don't depend on temp
- High degree of chemical inertness
- Water repellant (hydrophobic)
- Good dielectric strength
- Low surface tension
- *Ideal for many commercial applications*

# *Properties Ideal for Medicine*

- Hydrophobicity
- Stability at all temperatures
- High permeability to gases
- Transparency
- High flexibility
- Low rigidity
- Low wettability

## *Silica Uses*

- Pure fumed amorphous silica is used as a reinforcing agent in elastomer medical implants
- Crystalline silica is used as a component of building materials, ceramics, concretes, and glasses
- Both types are used as fillers in cosmetics and foods



# *Silicone Uses In Medicine*

- Fluids
  - Coatings for needles, sutures, syringes, and implanted devices
  - Instrument lubricants
- Gels
  - Fillers for breast and testicular implants
  - Gel sheeting
- Elastomers
  - Artificial joints and facial implants
  - Tubing, catheters, drains, and shunts

# *Biocompatibility*

- Silicones are used in medicine because of their extreme biologic inertness
- Hydrophobic properties
  - Cells cannot attach themselves to silicones
  - Chemicals and enzymes cannot gain sufficient contact to affect material
- Medical grade silicone has been the standard for biocompatibility against which all other compounds are compared

# *Biocompatibility Testing*

- Safety testing of gel and elastomer are first conducted in vitro and in experimental animals
- International organization for standards (ISO) and FDA specify extent and nature of testing needed to demonstrate safety of a device in contact with human tissues

# *Biocompatibility Testing*

Cytotoxicity

Hemolysis

Immunogenicity

Intracutaneous  
injection

Chronic toxicity

Sensitization

Pyrogenicity

Genotoxicity

Intramuscular  
implantation

# *Materials Testing*

- Oversight and regulations
  - American Society for Testing & Materials
  - International Organization for Standards
  - Food and Drug Administration
- ASTM test protocols performed by manufacturers on random batches of raw materials and/or finished products
  - sometimes performed on explants that have been retrieved

## *Relevant ASTM Protocols*

- F703: Standard specification for implantable breast prostheses
- D412: Test method for vulcanized rubber
- D1349: Temperature testing
- F748: Biological test methods
- F1251: Terminology for polymeric biomaterials
- F604: Specifications for silicone elastomers in medical applications

# *Mechanical Properties Tested*

- Tensile strength
- Percent elongation
- Breaking force
- Abrasion resistance
- Patch-bond strength
- No reliable or clinically relevant test to predict device failure or material fatigue

# *Breast Implant Design*

- Filler material
  - Silicone gel formulation
- Shell formulation
  - Shell is different for different fillers and for smooth vs. Textured surface
- Shell size and shape
  - Round vs. contoured
  - Low, medium, or high profile (base diameter)
  - Customized for reconstruction or deformities



# *Available Filler Materials*

- Saline
- Silicone gel
- Cohesive silicone gel
  - Formulation contains more crosslinks
  - Designed to minimize risk of gel extrusion and maintain shape if an implant ruptures

# *Shell Surface Options*

- Smooth or textured
- Texturing process
  - Inamed applies salt crystals to the outer surface of the shell
    - after curing, the crystals are removed
  - Mentor uses a reverse laminate
- Titanium coating available in Europe

# *Design Specifications*

- Each product has specifications that are specific to the product
  - The criteria by which a device design is developed, controlled, and evaluated
- Documented physical, chemical, and performance characteristics of a design
- Allowable variations for each characteristic

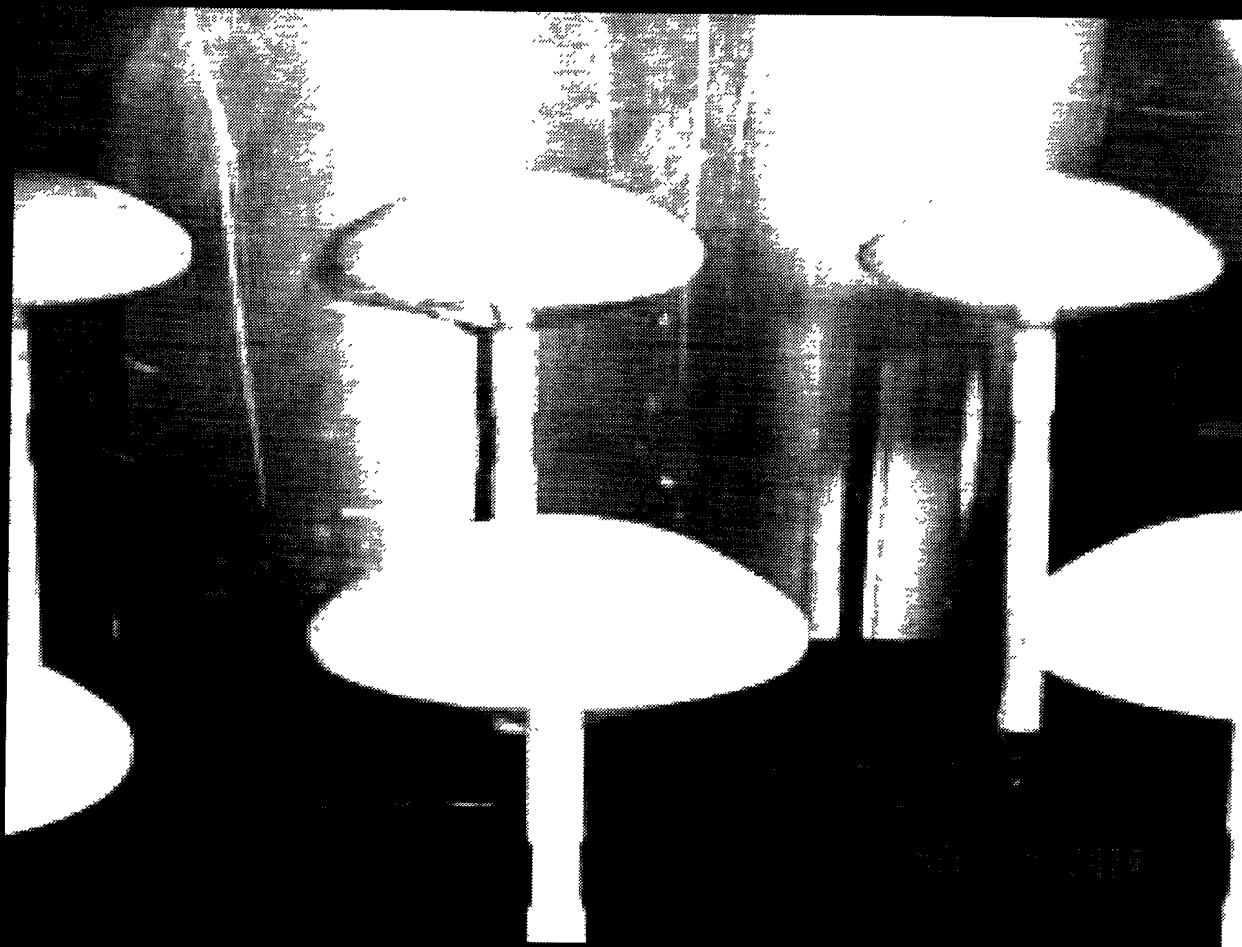
# *Breast Implant Design*

- Raw materials formulations (for gels and shells) are developed according to implant specifications
- An outside source supplies the raw materials to the implant manufacturer
- Materials are then inspected for purity and manufacturing consistency

# Breast Implant Design

- For each style, mandrels are produced for every possible volume
  - May range from ~50 cc to ~800 cc
- Mandrels are solid forms manufactured from either stainless steel or plastic
- The mandrel handle represents the location of the sealing patch
  - For saline implants with an anterior valve and posterior patch, two openings are needed

# Breast Implant Mandrels



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# *Silicone Elastomer Formulation*

- Different elastomer dispersions are used for different types of implants
- Room temperature vulcanization (RTV) dispersion is typically used for shells filled with saline
- High temperature vulcanization (HTV) dispersion is typically used for silicone gel-filled shells

# Silicone Elastomer Formulation

- Elastomer dispersion consists of linear silicone polymer (liquid), crosslinker, amorphous silica, and catalyst evenly distributed in a solvent (xylene)
- Manufacturing process involves:
  - 1) evaporation of the solvent
  - 2) curing: crosslinking reactions between the linear polymer and the crosslinker



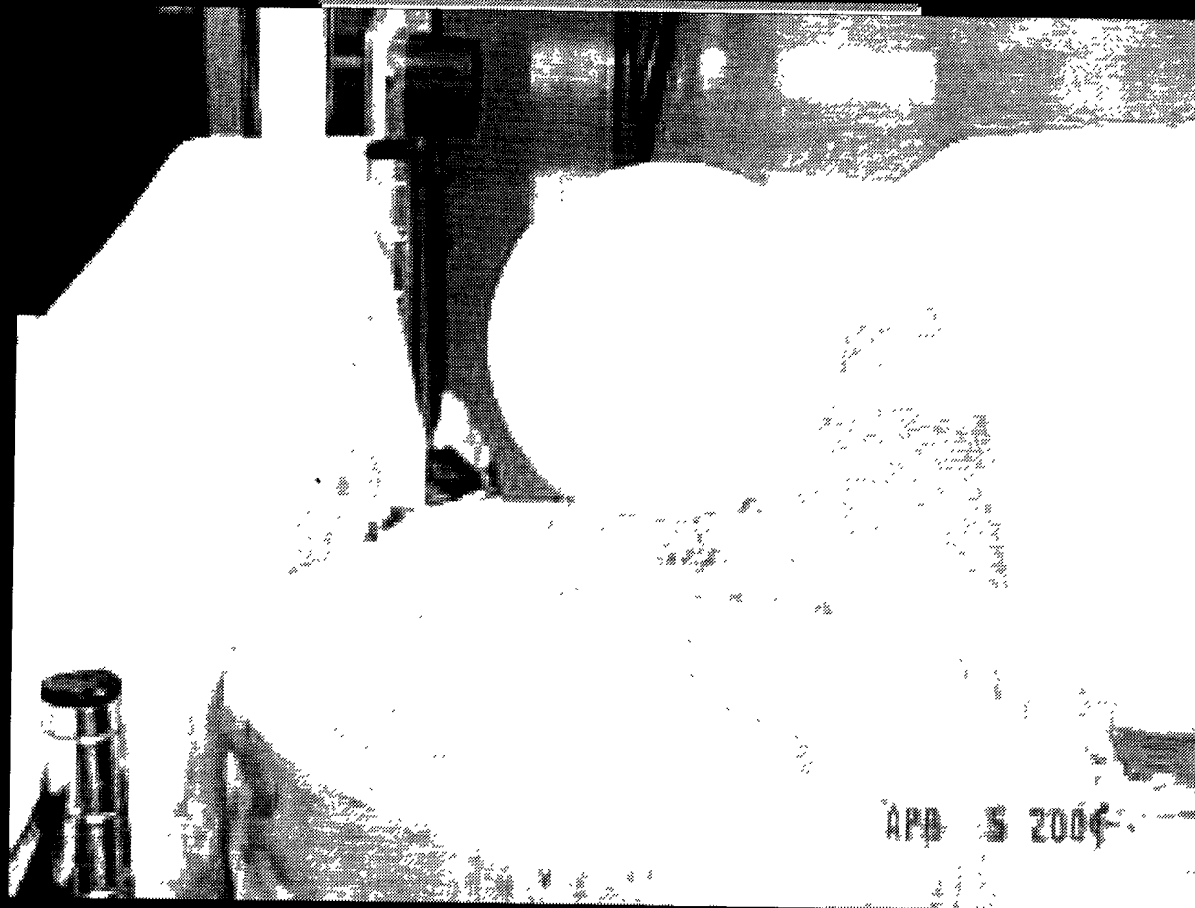
# *Silicone Gel Formulation*

- Supplied by outside source in 2 parts:
  - 1) Catalyst
  - 2) Crosslinker
- Two parts are mixed
- The vulcanization (curing) process begins and is completed inside the finished shell

# *Basic Production Process*

- Very labor-intensive
- The mandrel is dipped by hand into the elastomer dispersion and removed
- Only a thin layer of silicone remains after the solvent evaporates and curing begins
- Mandrel is re-dipped and removed until the shell reaches desired thickness

*Mandrel re-dipping and curing by  
heat/humidity continue until shell reaches  
desired thickness*



## *Barrier Layer*

- Current silicone gel implants contain a barrier layer designed to reduce the diffusion of gel through the shell
- Contains groups of large organic compounds that physically block smaller, unlinked molecules from passing through
- Proprietary barrier layer formulation is added between layers of elastomer
  - Fluorosilicone or diphenyl layer

*When the shells are finished, they are  
subjected to a final cure cycle in an oven*



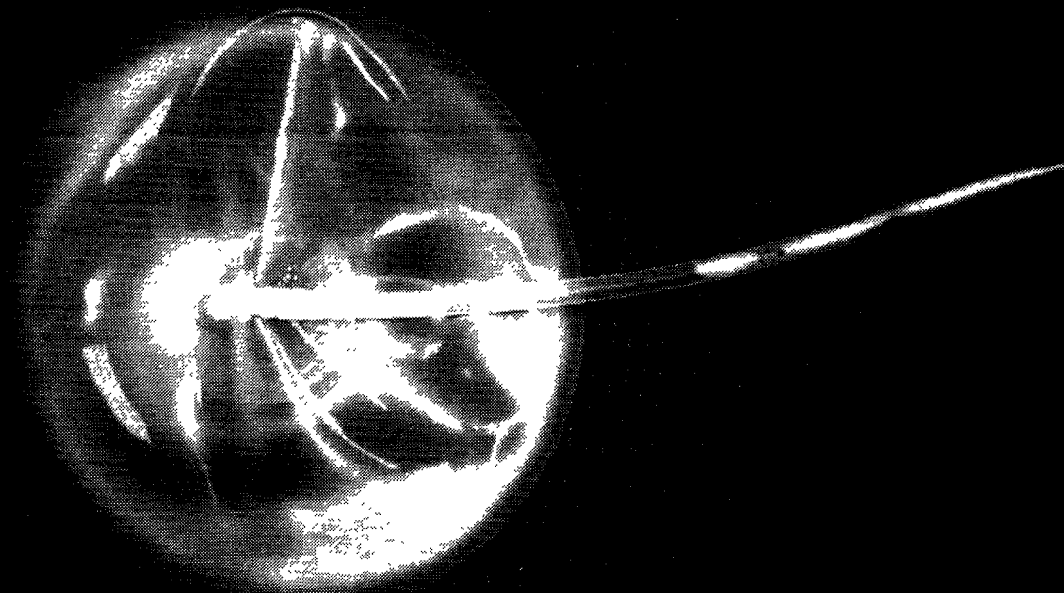
The shell then is peeled from the mandrel

# Assembly – Sealing

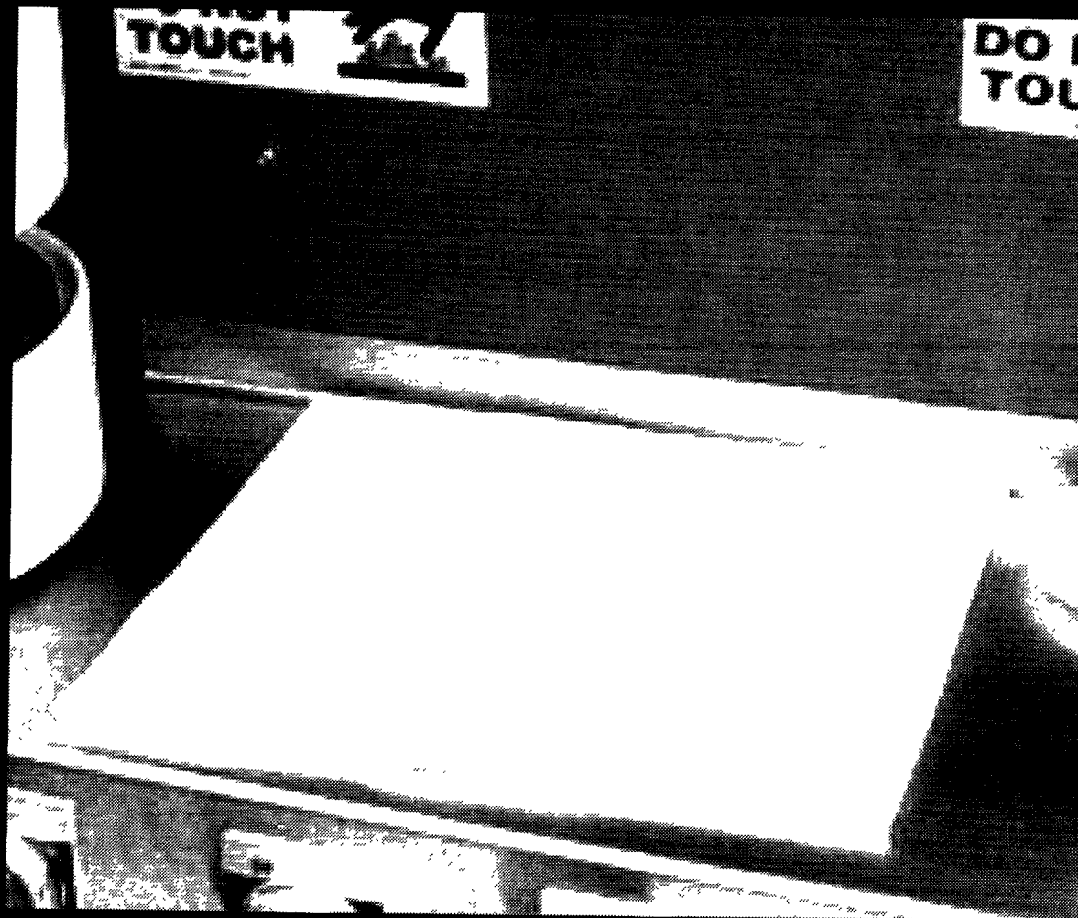
## *Inflatable implant*

- Posterior sealing patch and fill valve are bonded to shell via vulcanization
  - Sealing patch and valve may be separate or incorporated as a single unit
- Inflatable implants tend to have thicker shells for added strength

A valve is incorporated into devices  
designed to be filled with saline

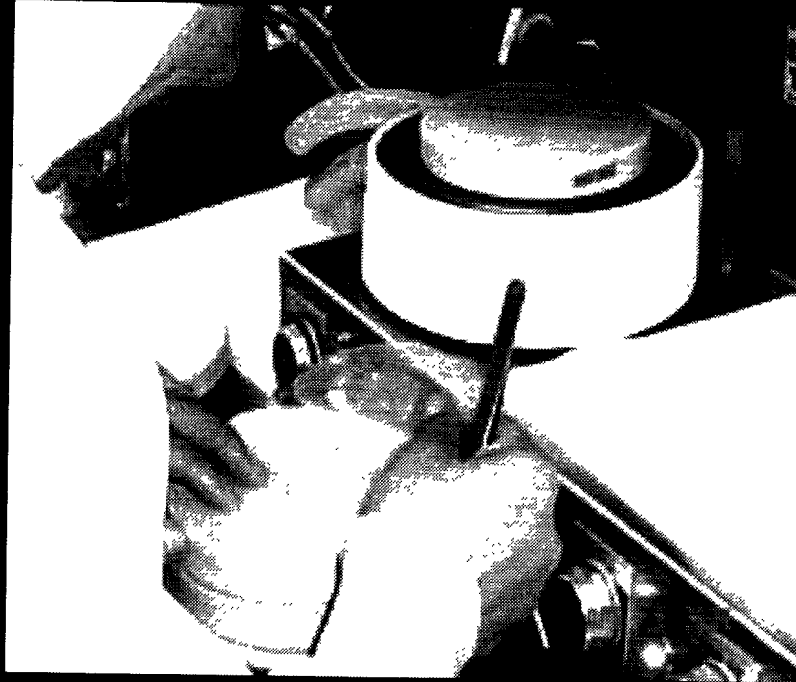


## Posterior sealing patch and unsealed shell





# Bonding of the sealing patch to the shell through vulcanization



Courtesy Mentor Corp.

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# *Assembly – Sealing & Filling*

## *Silicone Gel Implant*

- Gel is injected through a tiny needle hole in the patch
  - curing process continues inside the shell
- Fill hole is sealed with RTV silicone adhesive
- Filled implant is placed in a vacuum to remove air bubbles from the gel

# Testing And Quality Control

- FDA mandates that all medical device manufacturers have a system of clearly-defined quality controls
- Manufacturing process is validated to produce consistent quality
- Each completed implant is inspected according to quality specifications
- Each must meet all standards

# Quality Control Checks Are Performed Throughout Production



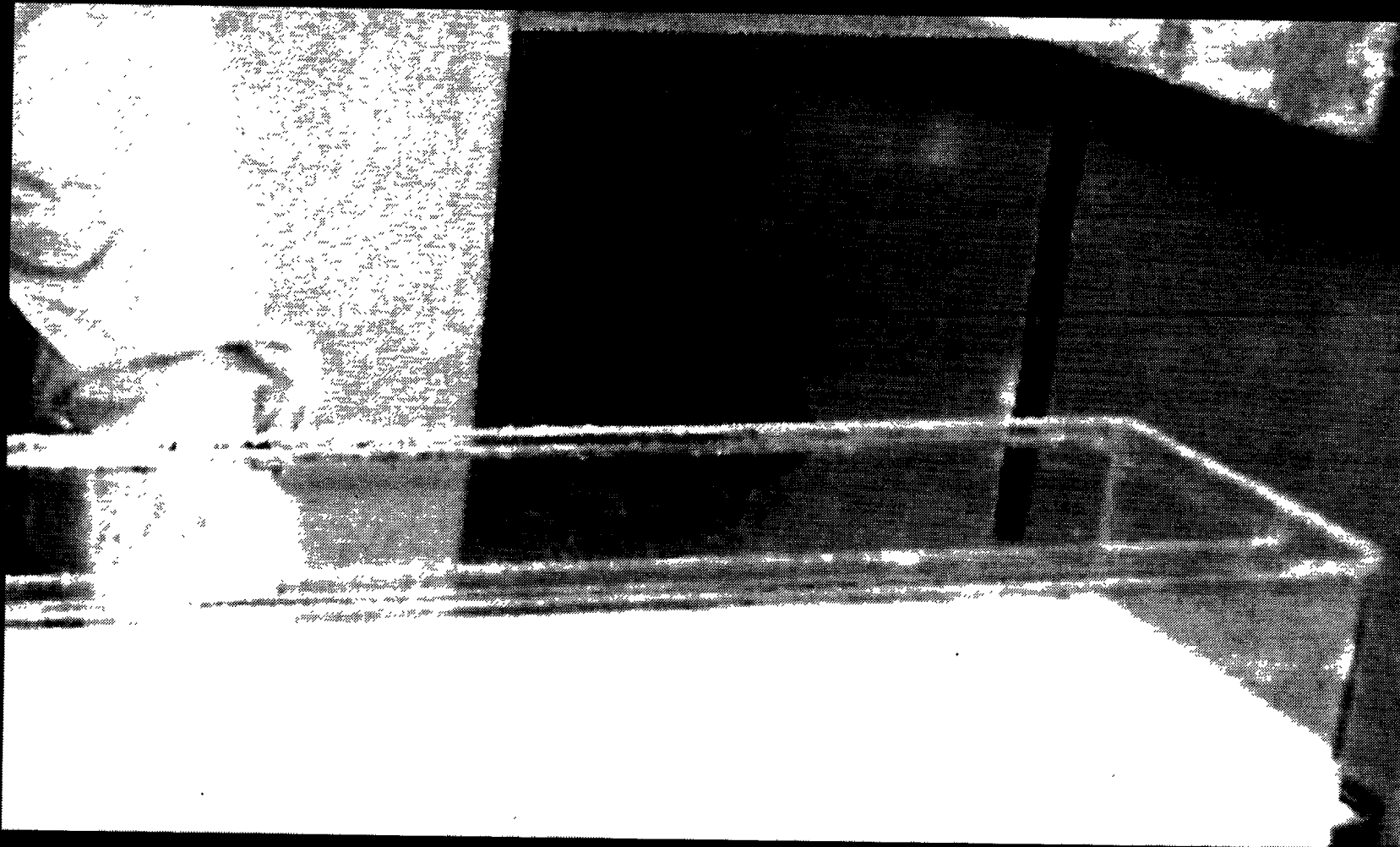
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# Implant Leak Test:



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## One Of Many Post-production Tests



# Packaging and Sterilization

Each implant is cleaned and double primary packaged (thermoform-within-thermoform)



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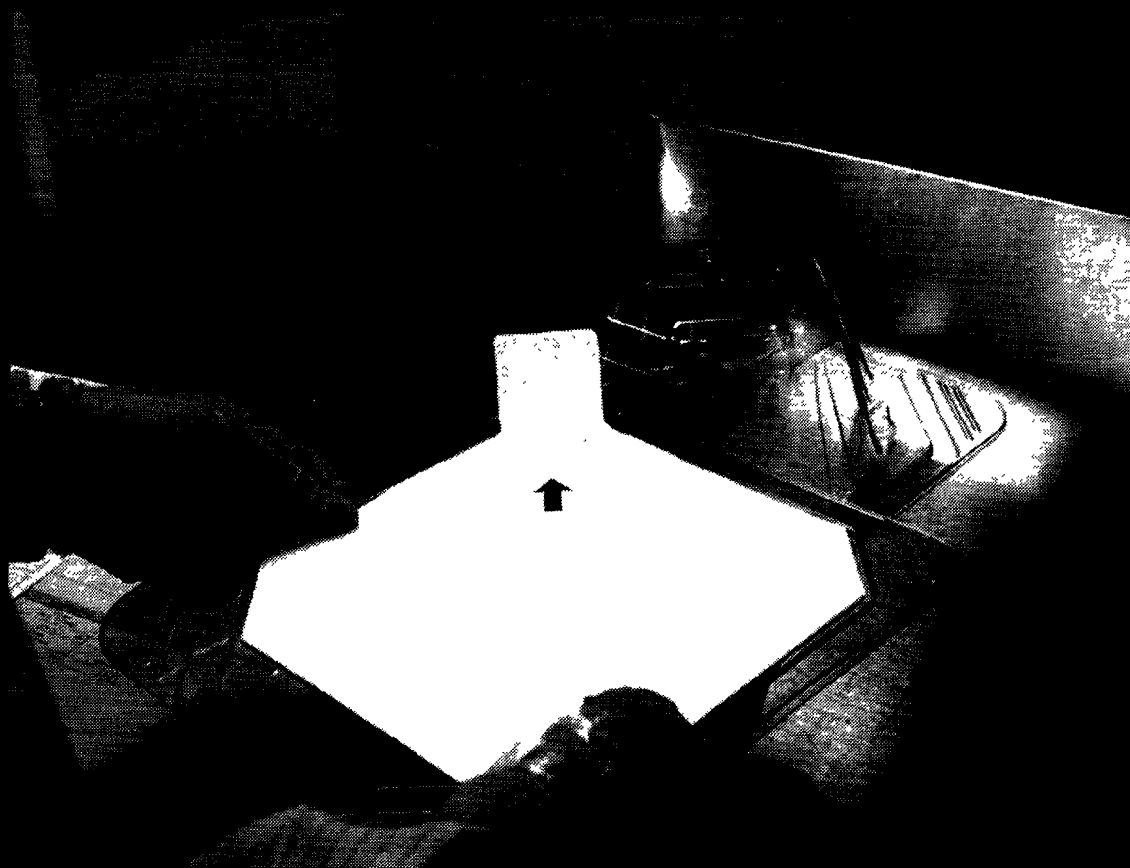
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*All package seals are checked for integrity*

*Sealed packages are sterilized by dry heat  
(high temperatures over time)*



Courtesy  
Mentor  
Corp.

# *Labeling And Tracking*

- After sterilization, products are quarantined and certified for quality
- Labels for patients and package inserts are placed in secondary packaging boxes and labeled
- Implants are released to product inventory
- Implants are tracked through labels returned by patients and surgeons